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Minnesota Board of Pharmacy

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Disciplinary Activity

We are pleased to report that there was no disciplinary activity during the months of March, April, and May.

Board Exams: Our Largest Ever

The Minnesota Board of Pharmacy gave its "written practical" as part of the overall Board exams on Wednesday, June 13, 2001. Approximately 160 candidates participated in the examination process. This number represents the largest number of candidates ever to participate in a single examination in Minnesota.

Since candidates for licensure now make their own appointments to take the North American Pharmacist Licensure Examination™ (NAPLEX®) and the Multistate Pharmacy Jurisprudence Examination™, not all candidates end up becoming licensed at the same time. The Board will be sending the pass/fail letters to candidates as soon as all three parts of the examination have been completed and scores are made available to the Board.

Potential employers of new licensees are cautioned not to schedule these individuals for work as pharmacists until the candidate has received notification of passing and has paid his or her original license fee. It would be a shame to jeopardize the license of one of these new graduates before they even receive it.

Exam candidates may work as pharmacist interns (as long as they are registered as interns with the Board), until they receive their examination results. Interns, however, are not allowed to perform professional functions without a currently licensed pharmacist present and on duty.

Employing Summer Interns

A number of pharmacy students have become eligible to work as pharmacy student-interns this summer. Many of these students will be seeking employment in order to obtain their required internship hours. Both pharmacy students seeking employment as interns and Minnesota pharmacists who might be interested in employing these students must remember that the students must be registered with the Minnesota Board of Pharmacy before they begin employment as interns, and the pharmacist acting as preceptor for these students must also be registered with the Board.

Every year it seems that individuals are found to be working in Minnesota as an intern based on an intern registration in another state. Registration as an intern in a neighboring state is not valid in Minnesota. If the student is employed in a Minnesota pharmacy, she or he must be registered as an intern in Minnesota. Pharmacists hiring pharmacy students must make sure that the student is properly registered with us and that a pharmacist registered with the Board as a preceptor is available to oversee the student's practical experience. Interns will not receive credit for their experience if the pharmacist overseeing their practical experience is not regis-

tered as a preceptor. Both internship registration forms and preceptor registration forms are available on the Board's Web site at www.phcybrd.state.mn.us.

Technician Registration Reminder

Board of Pharmacy inspectors continue to report an occasional individual working in the capacity of a pharmacy technician who is not properly registered with the Board as a technician.

In some cases, the newly employed individual is not familiar with the registration requirement, and the pharmacist employer has been negligent about making sure the individual is registered.

In some cases, technicians assume that if they are "certified" by the Pharmacy Technician Certification Board they somehow do not need to register with the Board of Pharmacy. On several occasions, Board inspectors have had to explain that certification does not eliminate the need for registration.

It is the responsibility of the pharmacist-in-charge of each pharmacy to make sure that all individuals performing functions that assist the pharmacist in the preparation and dispensing of prescriptions are registered with the Board as pharmacy technicians.

Pharmacists-In-Charge Are Mandatory

It has recently come to the attention of the Board that a dozen or more pharmacies in Minnesota are being operated without an individual pharmacist being identified as the "pharmacist-in-charge" of the pharmacy.

Minnesota Statute 151.34 indicates that it is unlawful to conduct a pharmacy without a pharmacist-in-charge. A violation of this type is grounds for disciplinary action, which could involve the closure of the pharmacy.

The Board is very concerned about the apparently growing number of pharmacies that are attempting to operate without anyone being in a position of responsibility at the pharmacy. The Board does not relish the idea of putting a pharmacy out of business because of a lack of a pharmacist-in-charge, but it will consider all of its options, including closure, if pharmacies continue to operate without a pharmacist-in-charge.

Electronic Prescribing Not Foolproof

The Board has recently learned of a serious medication error involving a computerized prescriber order entry system. A prescriber using a handheld computerized order entry device intended to order a prescription for Ocuflax for a patient with pinkeye. Unfortunately, the prescriber selected the wrong drug and caused an order for Occlusal-HP to be ordered instead. The order was electronically sent to a pharmacy's computer with directions to "use daily as directed." Occlusal-HP is a 17% solution of a salicylic acid used for removing warts. Significant damage to the patient's eyes could have resulted had the prescription been dispensed as ordered. Fortunately, the pharmacist counseled the patient and when the patient

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Study Shows Sharp Increase in Prescription Drug Misuse Costs and Morbidity

A study published in the March/April 2001 issue of the *Journal of the American Pharmaceutical Association* estimates that prescription drug misuse costs the health care system \$177.4 billion and results in 218,000 deaths each year; a significant increase over the findings of a 1995 study conducted by Jeffrey A. Johnson, PhD, and J. Lyle Bootman, PhD, of the College of Pharmacy, University of Arizona, which estimated such costs to be \$76 billion and the number of deaths approximately 198,000.

Study authors Frank R. Ernst, PharmD, and Amy J. Grizzle, PharmD, of the College of Pharmacy, University of Arizona, Tucson, found that of the \$177.4 billion spent, hospital and long-term care facility admissions accounted for \$121.5 billion (69%) and \$32.8 billion (18%), respectively. Another 13.8 billion (8%) was spent on physician visits, \$5.8 billion (3%) on emergency department visits, and \$3.5 billion (2%) on additional treatments.

According to the study, the majority of the cost increases appeared to result from estimates of hospital and long-term care admission costs, which were more than twice the 1995 estimates. Further, Ernst and Grizzle estimated the mean cost of treatment failure to be \$977. For new medical problems, the mean cost was estimated at \$1,105, and the cost of a combined treatment failure and resulting new medical problem was \$1,488. They identified the most significant drug-related problems to be untreated indication, improper drug selection, subtherapeutic dosage, failure to receive drugs, overdosage, adverse drug reactions, drug interactions, and drug use without indication.

The authors' research of prior literature demonstrated that "costs associated with drug-related morbidity and mortality exceed the expenditures for initial drug therapy; that is, the total cost of drug-related morbidity and mortality exceeds the cost of the medications themselves."

They concluded that "drug-related morbidity and mortality continue to pose a serious medical and economic problem for society" and recommended that "more attention be directed toward developing solutions that reduce preventable morbidity, mortality, and costs associated with drug-related problems."

DEA Clarifies CII Prescription Faxing

The US Drug Enforcement Administration (DEA) published a final rule in the January 11, 2001 *Federal Register*,

which clarifies that prescriptions for Schedule II narcotic substances for patients enrolled in hospice care certified by Medicare under Title XVIII or licensed by the state may be transmitted by facsimile. 21 CFR 1306.11(g) originally provided that a pharmacy could dispense a Schedule II narcotic substance pursuant to a prescription transmitted via fax for a patient "residing in a hospice certified by Medicare. . . or licensed by the state."

According to the DEA, this language was perceived by many as requiring that the patient reside in a hospice facility to the exclusion of other health care settings, such as home hospice care. The new language clarifies that fax transmission is allowed for a patient "*enrolled in a hospice care program* certified by Medicare. . .," [italics added] making it clear that Schedule II narcotic prescriptions may be faxed for patients enrolled in recognized hospice programs, regardless of where the patient resides.

This amendment became effective February 12, 2001. For further information, contact Patricia M. Good, chief, Liaison and Policy Section, Office of Diversion Control, DEA, Washington, DC 20537, 202/307-7297.

FDAMA Compounding Legislation Ruled Unconstitutional

On February 6, 2001, the United States Court of Appeals for the Ninth Circuit ruled the pharmacy compounding section of the Food and Drug Administration Modernization Act of 1997 (FDAMA) unconstitutional and, therefore, unenforceable. The court upheld the US district court's ruling that restrictions on commercial speech found in Sections 353A(a) and (c) violate the First Amendment.

Sections 353A(a) and (c) of the FDAMA allowed the compounding of drugs as long as the compounding pharmacy, pharmacist, or physician did not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The advertising of compounding services in general was not prohibited. The lawsuit, which was filed by several compounding pharmacies, claimed the advertising provisions violated the First Amendment.

"NABP is reviewing the court decision to understand its impact on current state and federal regulations," states NABP Chairman Jerry Moore. "In the most dramatic sense, it could be a return to the situation that existed prior to the compounding legislation's adoption. If this is the case, NABP would advise states to continue their efforts to distinguish compounding from manufacturing and work cooperatively with the Food and Drug Administration (FDA) to resolve manufacturing complaints."

Section 353A was intended to curtail the manufacturing of products under the guise of compounding. In addition to placing advertising restrictions on compounding services, it regulated the types and characteristics of bulk drug substances and ingredients that may be used in compounding and limited the amount of compounded product that may be distributed out of state. The law specifically designated NABP as a consultant to the Secretary of the Department of Health and Human Services (HHS) in developing a memorandum of understanding for states to use when compounded drugs are distributed across state lines and mandated that an NABP representative be appointed to an advisory committee to assist HHS in developing regulations.

CybeRx-Smart Coalition Offers Tips for Online Rx Safety

Adhering to a few simple, common sense precautions, such as looking for the Verified Internet Pharmacy Practice Sites™ (VIPPS™) seal, offers consumers significant protection when purchasing prescription medicines online, says the CybeRx-Smart Safety Coalition. Organized by the US Food and Drug Administration (FDA) and comprised of 14 government, professional, and industry related organizations, including NABP, the Coalition has launched a national public service campaign featuring public service radio announcements, news releases, and an information brochure that appears on the FDA Web site at www.fda.gov.

Through the efforts of the Coalition, FDA has made a significant commitment to educating consumers about the “do’s and don’ts” of buying prescription medication online. Consumers are advised to:

- Meet with their doctors to obtain any new prescription;
- Look for the VIPPS seal to ensure they are dealing with a legitimate pharmacy;
- Buy only from US-based sites;
- Look for easy-to-find and understandable privacy and security policies; and
- Use the same standards when purchasing prescription medications online as you would when selecting any reputable pharmacy.

Consumers are also encouraged to report any site they believe to be unlicensed or a problem to the FDA.

FDA’s future plans to widely promote the Coalition brochure include the distribution of a card with every tax refund check listing the new brochure; radio public service announcements (an audience of over five million has been

reached to date); a banner page on the FDA Web site; and an exhibit booth at several professional meetings during 2001.

Member organizations of the CybeRx-Smart Safety Coalition are the American Pharmaceutical Association, American Society of Consultant Pharmacists, American Society of Health-System Pharmacists, CornerDrugstore.com, CVS.com, drugstore.com, Federal Trade Commission, NABP, National Association of Chain Drug Stores, National Community Pharmacists Association, National Council on Patient Information and Education, National Patient Safety Foundation, PlanetRx.com, and the FDA.

The Coalition brochure is posted at www.fda.gov/cder/drug/consumer/buyonline/guide.htm.

DEA Offers New Controlled Substance Regulation Manual for Pharmacists

The US Drug Enforcement Administration (DEA) announced the availability of a new publication for pharmacists entitled *Pharmacists Manual, An Information Outline of the Controlled Substances Act of 1970*.

The publication is available on DEA’s Web site at www.deadiversion.usdoj.gov or from DEA Diversion Field Offices.

“DEA is hopeful that this manual will prove to be a valuable resource and will assist pharmacists in understanding the Controlled Substances Act of 1970 and its implementing regulations as they pertain to pharmacy practice,” says Patricia M. Good of the DEA Office of Diversion Control.

For further information contact the Liaison Unit of the DEA Office of Diversion Control at 202/307-7297.

Continuing Education Available on FDA Web Site

The US Food and Drug Administration’s (FDA) Center for Drug Evaluation and Research (CDER) now offers free continuing education programs for pharmacists and physicians via its Web site.

The first program, entitled *New Drug Development in the United States*, provides an overview of the FDA’s role in the new drug development process by discussing various aspects of the Investigational and New Drug Application (IND/NDA) process, including drug testing in the laboratory and in patients, the importance of the Prescription Drug User Fee Act, the FDA Modernization Act, generic drugs, and post-marketing surveillance.

Interested individuals may access this one-credit hour program at www.fda.gov/cder/learn/CDERLearn/default.htm.

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indicated that the physician had instructed that it be used in each eye, the pharmacist immediately recognized that an error had occurred.

This near tragedy points out the need for patient counseling and underscores the concept that "use as directed" is never appropriate. Pharmacists are urged to counsel all patients but especially those receiving new prescriptions.

Statistics of Interest (Count as of March 14, 2001)

Pharmacists

Type	Total Pharmacists	Male	Female	7-County Metro Area
Active	5,462	3,052	2,410	2,381
Inactive	72	46	26	18
Emeritus	104	88	16	40

Male Pharmacists

Type	Greater Minnesota	Out-of-state	7-County Metro Area
Active	1,163	694	1,195
Inactive	10	24	12
Emeritus	29	24	35

Female Pharmacists

Type	Greater Minnesota	Out-of-state	7-County Metro Area
Active	623	601	1,186
Inactive	1	19	6
Emeritus	1	10	5

Work	In-state	Out-of-state
Retail	2,942	1,001
Hospital	965	470
Other	914	931

Technicians

Total Technicians	7-County Metro Area
4,707	2,512
Total Male Technicians	7-County Metro Area
573	430

Total Female Technicians	Greater Minnesota	Out-of-state	Metro Area
4,134	2,047	5	2,082
Work Retail	Hospital	Other	
3,972	1,269	228	

Pharmacies (1,369)

	Total	7-County Metro Area
Community Pharmacy/Non-chain	534	149
Community Pharmacy/Chain	491	271
Hospitals		
Public	31	4
Private	113	22
Satellite	2	1
Parenteral-Enteral/		
Home Health Care	59	19
Nursing Home	69	14
Nuclear	7	3
Non-resident	211	0
Federal	8	1
Total Wholesalers	In-state 348	Out-of-state 377
Total Manufacturers	In-state 108	Out-of-state 141
Total Medical Gas Distributors	In-state 29	Out-of-state 6
Controlled Substance Researchers	In-state 112	Out-of-state 1
Interns	Preceptors 495	

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